



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Overview of comments on draft Community herbal monograph on *Lavandula angustifolia* Miller, flos (EMA/HMPC/143181/2010)

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Lavandula angustifolia* Miller, flos as released for public consultation on 15 February 2011 until 15 August 2011.

	Organisations and/or individuals
	AESGP, Brussels, Belgium



Table 2: Discussion of comments

General comments to draft document

Interested party	Comment and Rationale	Outcome
AESGP	AESGP in principle welcomes the development of the above-mentioned Community herbal monograph which, by providing harmonised assessment criteria for Lavandula flos-containing products, should facilitate mutual recognition in Europe. We have the following specific comments.	

SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.2 Posology and method of administration	AESGP	<p>Posology and use in children</p> <p>We propose to delete the recommendation not to use Lavender flower in children under 12 years of age and insert a dosage recommendation of "<i>approximately 1 g in 150 ml of water: 3 times daily</i>".</p> <p><u>Reasons:</u></p> <p>Schilcher [1] describes the use of Lavender flower in children, e.g. in a combination containing 30 % Lavender flower used as a herbal tea. Depending on the age, 1-3 cups per day are recommended.</p> <p>Lavender flower is also included in the preparation Kneipp® Nerven- & Schlaf Tee (consisting of Melissa leaf, Valerian root, Lavender flower and Peppermint leaf) which corresponds to the German Standardzulassung with the indication "nervous agitation, difficulties to fall asleep". There is no restriction of age.</p> <p>Schilcher [1] also mentions the use of Lavender flower as a bath additive for children (50-100 g flowers for one bath).</p>	There indeed exists a long-lasting tradition for the use of lavender flower. However no lower age limit is given. Age limits cannot be arbitrarily chosen.
4.4 Special warnings and precautions for use	AESGP	As stated above, the recommendation not to use the preparation in children under 12 years of age should be deleted.	The age limit of 12 years is maintained.

References:

[1] Schilcher H, Dorsch W. Phytotherapie in der Kinderheilkunde. 4th edition. Stuttgart:WVG. 2006:72-76.